

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the Adoption of New)	NOTICE OF PUBLIC HEARING
Rules I through VIII pertaining to)	ON PROPOSED ADOPTION
newborn hearing screening)	

TO: All Interested Persons

1. On January 14, 2008, at 2:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the Wilderness Room, 2401 Colonial Drive, Helena, Montana, to consider the proposed adoption of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process (including reasonable accommodations at the hearing site) or who need an alternative accessible format of this notice. If you need an accommodation, contact the department no later than 5:00 p.m. on January 7, 2008. Please contact Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena MT 59620-2951; telephone (406)444-9503; fax (406)444-9744; e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

RULE I DEFINITIONS (1) "Health care provider" means a person licensed in the state of Montana to provide health care services to pregnant women and/or newborn infants and who is the primary health care provider in attendance at the birth of a newborn infant born outside of a hospital or health care facility. The term includes direct-entry midwives.

(2) "Hospital or health care facility that provides obstetric services" means any hospital or health care facility licensed by or operating in the state of Montana that routinely provides or holds itself out as providing obstetric services, without regard for the number of births actually occurring in that hospital or health care facility on an annual basis.

(3) "Newborn" means any infant from birth through 28 days of age.

AUTH: 53-19-402, MCA

IMP: 53-19-402, 53-19-404, MCA

RULE II NEWBORN HEARING SCREENING EDUCATION (1) Each licensed hospital and health care facility shall provide education to the parents of any newborn born in the hospital or health care facility or transferred to the hospital or health care facility from the newborn's place of birth, unless the newborn has previously been provided a hearing screening test by a hospital or health care facility from which the newborn was transferred, on:

- (a) hearing loss;
 - (b) the importance of early hearing screening; and
 - (c) the process for conducting newborn hearing screening
- (2) Each licensed health care provider in attendance at any birth outside of a hospital or health care facility shall provide education to the newborn's parents on:
- (a) hearing loss;
 - (b) the importance of early hearing screening; and
 - (c) the process for conducting newborn hearing screening.
- (3) Each hospital, health care facility, and health care provider required to provide newborn hearing screening education shall comply with education protocols developed by the department and shall use educational materials provided by the department. Protocols and educational materials may be obtained from the Department of Public Health and Human Services, Newborn Screening Program, Children's Special Health Services Section, Family and Community Health Bureau, P.O. Box 202951, Helena, Montana 59620-2951.

AUTH: 53-19-402, MCA

IMP: 53-19-404, MCA

RULE III NEWBORN HEARING SCREENING - REFERRALS FOR NEWBORNS BORN OUTSIDE OF HOSPITALS OR HEALTH CARE FACILITIES

(1) Each health care provider who is required to provide newborn hearing screening education shall also provide referral information to the parents of any newborn who was born outside of a hospital or health care facility. The referral information shall identify the hospitals, health care facilities, and other health care providers in the region that are able to provide hearing screenings for newborns.

AUTH: 53-19-402, MCA

IMP: 53-19-404, MCA

RULE IV NEWBORN HEARING SCREENING PROTOCOLS - HOSPITALS AND HEALTH CARE FACILITIES

(1) Each licensed hospital or health care facility that provides obstetric services shall establish a newborn hearing screening program in order to ensure that a hearing screening is provided for each newborn born in the hospital or health care facility or transferred to the hospital or health care facility from the newborn's place of birth, unless the newborn was previously provided a hearing test by a hospital or health care facility from which the newborn was transferred.

(a) An initial hearing screening must be performed prior to the infant's discharge from the hospital or health care facility.

(b) If the results of the initial hearing screening were inconclusive or indicated a possible hearing loss, a second screening must be performed prior to the newborn's discharge from the hospital or health care facility, if possible. If a second hearing screening cannot be performed prior to the infant's discharge from the hospital, the hospital or health care facility must, prior to the discharge, work with the newborn's parents to schedule a second hearing screening for the newborn. The second screening shall be scheduled at the hospital or health care facility from which the newborn is being discharged. It shall be scheduled to occur within 30 days of

the newborn's birth.

(2) Each hospital or health care facility shall use equipment designed to perform hearing screenings that utilizes either otoacoustic emissions (OAE) or auditory brainstem response (ABR) technology. Hearing screening equipment shall be maintained, calibrated, and used in strict conformance with manufacturers' guidelines.

(3) Newborn hearing screening shall be performed by staff members who are properly trained to conduct and interpret the tests and shall be performed in strict conformity with the testing protocols set by the equipment manufacturer.

AUTH: 53-19-402, MCA

IMP: 53-19-402, 53-19-404, MCA

RULE V REPORTING NEWBORN HEARING SCREENING RESULTS - PARENTS - PRIMARY CARE PROVIDERS (1) The hospital or health care facility shall document all hearing screening results in the newborn's chart and shall provide the hearing screening results to the parents of the newborn on the newborn's Report Card form. If the newborn hearing screening indicates a possible hearing loss, the written notification of results to the newborn's parents must include a recommendation for an audiological assessment.

(2) The hospital or health care facility shall also provide the newborn's primary care provider with written notification of the results of the newborn hearing screening. If the newborn hearing screening indicates a possible hearing loss, the written notification of results sent to the newborn's primary care provider must include a recommendation for an audiological assessment.

AUTH: 53-19-402, MCA

IMP: 53-19-404, MCA

RULE VI REPORTING TO THE DEPARTMENT REGARDING NEWBORN HEARING SCREENING AND EDUCATION (1) Each hospital and health care facility required to provide newborn hearing screenings must make a report to the department each month using the department's designated reporting software regarding newborn hearing screenings.

(2) Each hospital and health care facility shall enter the following information by the 15th day of each month for each newborn born in or transferred to the hospital or health care facility during the preceding month:

(a) the newborn's full name, date of birth, gender, mother's maiden name, and the location of the newborn's birth;

(b) that the education protocol and educational materials developed by the department on newborn hearing screening were provided to the parents of the newborn;

(c) whether the facility did or did not provide a complete hearing screening to the newborn as required in [RULE IV];

(d) for any newborns not fully screened, a statement of any reason(s) the newborn has not been not fully screened;

(e) if the newborn was provided an initial screening prior to discharge, and

the results of that screening indicated possible hearing loss, the date scheduled for the follow-up hearing screening;

(f) all of the newborn's hearing screening results; and

(g) contact information for the newborn's primary care provider if the initial or follow-up hearing screening(s) indicated possible hearing loss.

(3) If a newborn was discharged from a hospital or health care facility after an initial screening that indicated a possible hearing loss, the hospital or health care facility shall file an updated screening report regarding the newborn's hearing screening status by the 15th day of the month immediately following the appointment date set for the second screening.

(4) By the 15th day of each month, each hospital and health care facility shall provide the department a signed facsimile copy of any completed parent refusal form for each baby born in the previous month who did not receive newborn hearing screening or who did not have complete hearing screening because the parent refused the initial or follow-up screening. The refusal form used by the hospital or health care facility must contain at minimum the content of the "Parental Attestation of Refusal of Newborn Hearing Screening" form distributed as a suggested template by the department.

AUTH: 53-19-402, MCA

IMP: 53-19-404, MCA

RULE VII HEALTH CARE PROVIDERS - REPORTING TO THE DEPARTMENT REGARDING EDUCATION AND REFERRAL INFORMATION

(1) Each licensed health care provider in attendance at any birth occurring outside a hospital or health care facility shall file a report with the department that documents:

(a) the newborn's full name, date of birth, gender, mother's maiden name, and the location of the newborn's birth;

(b) that the education protocol and educational materials developed by the department on newborn hearing screening were provided to the parents of the newborn;

(c) that referral information has been provided to the newborn's parents which identifies the hospitals, health care facilities and other health care providers in the area that are able to provide hearing screenings for newborns.

(d) that the newborn's primary care provider, if other than the health care provider attending the birth, has been notified that newborn hearing screening has been provided to the newborn's parents.

(2) The report shall be made to the department by the 15th day of each month for the babies delivered in the previous month on a form available from the Department of Public Health and Human Services, Newborn Screening Program, Children's Special Health Services Section, Family and Community Health Bureau.

AUTH: 53-19-402, MCA

IMP: 53-19-404, MCA

RULE VIII AUDIOLOGISTS - REPORTING OF AUDIOLOGICAL

ASSESSMENTS TO DEPARTMENT - PARENTAL CONSENT FOR REFERRAL TO THE MONTANA SCHOOL FOR THE DEAF AND BLIND (1) Each licensed

audiologist to whom an infant is referred for audiological assessment following a newborn hearing screening shall file a report with the department each month regarding the results of the infant's audiological assessment. The report shall be filed using the department's designated reporting software. The audiologist shall enter and report the following information by the 15th day of each month for each infant assessed during the previous month:

(a) the newborn's full name, date of birth, gender, mother's maiden name, and the location of the newborn's birth;

(b) the name and address of the hospital or health care facility in which the baby was born or transferred to or the name and address of the health care provider attending the birth;

(c) complete audiological assessment results for the newborn, including current hearing status.

(2) Each licensed audiologist to whom an infant is referred for audiological assessment following newborn hearing screening shall request written authorization from the infant's parents for the audiologist to provide the infant's identifying information and test results to the department for subsequent referral for intervention services to the Montana School for the Deaf and Blind.

(a) Authorization shall be obtained on authorization forms approved and provided by the department.

(b) The audiologist shall submit a copy of the signed authorization form to the department by facsimile or as a scanned electronic attachment within three days of the date it is signed.

AUTH: 53-19-402, MCA

IMP: 53-19-404, MCA

4. These rules make newborn hearing screening mandatory instead of permissive for all infants born in Montana in hospitals or health care facilities and for all infants born outside a hospital or health care facility who are attended to by a health care provider licensed to provide health care services to pregnant women and/or newborn infants outside of a hospital or health care facility. House Bill 117 passed in the 2007 Montana legislative session (2007 Laws of Montana Chapter 251) amended Title 53, chapter 19, part 4, Newborn Hearing Screening of the Montana Code Annotated (MCA). The changes require: (1) newborn hearing screening; (2) parental education regarding hearing loss, the importance of early intervention in cases in which a hearing loss is detected and the methods used to conduct newborn hearing screening; (3) referral for further testing and follow-up by three months of age in cases in which the initial screening identifies a possible hearing loss; and (4) that screening results and audiological assessments be reported to the department and, in cases in which a hearing deficiency has been identified, shared with the Montana School for the Deaf and Blind.

The objective of the Montana Legislature in passing House Bill 117 was to make sure that all infants born in Montana are afforded the best opportunity for early

identification of, and timely receipt of intervention for, hearing loss to prevent developmental delays and academic failures associated with late identification of hearing loss. An additional objective is to provide necessary public health surveillance information to effectively plan, establish, and evaluate a comprehensive system of appropriate services for infants and children who are deaf or hard of hearing. These new rules represent the minimum requirements reasonably necessary to give effect to the Legislature's intent and to provide the greatest opportunity for healthy lives for Montana's children.

RULE I DEFINITIONS

Terms are included in the Rule to clarify which health care professionals and health service entities are subject to the provisions of the law and its promulgated rules.

RULE I(1): The term "Health care provider" is used within these rules to specify the licensed health care professional who provides health care services to pregnant women and/or newborn infants and who is the primary health care provider in attendance at the birth of a newborn infant born outside of a hospital or health care facility. The definition specifies that direct-entry midwives are included in this term. The term does not include unlicensed attendants at births.

RULE I(2): The term "Hospital or health care facility that provides obstetric services" is used within these rules to include any hospital or health care facility licensed by or operating in Montana that routinely provides or holds itself out as providing obstetric services, no matter how many or how few births occur in that hospital or health care facility in a year. That is, a hospital or health care facility that provides obstetric services for only one birth per year is covered by the provisions of the rules.

RULE I(3): The term "Newborn" defines the infant who is the subject of the newborn hearing screening rules as being a child in the age range from birth through 28 days of age.

RULE II NEWBORN HEARING SCREENING EDUCATION

Parental education about the importance of newborn hearing screening to detect possible hearing loss is crucial to parental acceptance that newborn hearing screening is an appropriate and important standard of newborn care, that the hearing screening should be performed prior to hospital discharge and that follow-up screening should be completed as an outpatient if it is indicated and if it was not possible to complete it before discharge. The department shall provide an education protocol and educational materials to be used by hospitals, health care facilities, and health care providers as defined in Rule I to ensure that all parents are apprised of the same minimum level of information.

RULE II(1) addresses the requirement that each licensed hospital and health care facility provide education about hearing screening and hearing loss. The rule requires licensed hospitals and health care facilities to educate parents of newborns

on hearing loss, the importance of the newborn hearing screening and the benefits of early intervention in cases in which a hearing loss is detected and about how newborn hearing screening is conducted. That education must be provided to the parents of babies born in their hospital or facility and to the parents of any baby transferred into that hospital or facility, unless the baby transferred to the hospital or facility has already received newborn hearing screening prior to the transfer.

RULE II(2) requires any health care provider attending a birth outside a hospital or health care facility to provide education to the parents of that baby about hearing loss, the importance of newborn hearing screening, the benefits of early intervention in cases in which a hearing loss is detected, and about how the newborn hearing screening is conducted.

RULE II(3) establishes that the department shall provide a standard parental education protocol and educational materials for each hospital, health care facility, and health care provider defined in Rule I. The education protocol and educational materials can be accessed through the department's Newborn Screening Monitoring Program.

RULE III NEWBORN HEARING SCREENING – REFERRALS FOR NEWBORNS BORN OUTSIDE OF HOSPITALS OR HEALTH CARE FACILITIES

Not all health care providers may have hearing screening equipment in their practices. For this reason, health care providers must provide not only education about hearing loss, the importance of newborn hearing screening, and about how newborn hearing screenings are conducted, but must also provide referral information for parents of the babies whose births they attend outside of hospitals or health care facilities, so the parents may arrange for their newborn's hearing screening in their region. The referral information must identify the hospitals, health care facilities, and other health care providers in the region that are able to provide newborn hearing screenings in accordance with Rule IV. The department will assist the health care providers in providing this information.

RULE IV NEWBORN HEARING SCREENING PROTOCOLS – HOSPITALS AND HEALTH CARE FACILITIES

The department's newborn hearing screening program has adopted the national "1-3-6" screening, assessment, and intervention standard for provision of services. It is of crucial importance that newborn hearing screenings be completed by one month of age. If the screenings indicate that the baby may have a hearing loss, an audiological examination must be completed by no later than three months of age. If the audiological assessment indicates that the baby is deaf or hard of hearing, it is critical to the language and social development of the baby that intervention be initiated before the child reaches six months of age. The first step in this continuum of highly time-sensitive services relies on the hospitals and health care facilities to ensure that all babies born under their auspices are completely screened. This rule addresses the newborn hearing screening requirements that must be met by

hospitals and health care facilities defined in Rule I.

RULE IV(1) specifies that each hospital and health care facility establish a newborn hearing screening program to ensure that each newborn born in the hospital or health care facility receives hearing screening. This screening requirement applies to all babies transferred into the hospital or health care facility if newborn screening was not performed prior to the transfer.

Because it is often difficult to complete screenings once the baby has been discharged from the hospital or health care facility, national standards and Rule IV(1)(a) require that newborn hearing screening be performed prior to hospital discharge.

RULE IV(1)(b) requires that a second hearing screening be performed prior to discharge if the first screening was inconclusive or indicated a possible hearing loss. If the second screen cannot be performed prior to the infant's discharge, the hospital or health care facility must work with the parents prior to discharging the newborn from the hospital to set an appointment within 30 days of birth for the parents to bring the baby back for a second hearing.

Standard newborn hearing screening equipment must be in place across the state to ensure that all babies are screened in a comparable way. National standards for newborn screening methods are applied to Montana's statewide program. Rule IV(2) specifies that the screening must be conducted using either otoacoustic emissions (OAE) or auditory brainstem response (ABR) technology. Those are the only two technologies currently available to test a newborn's hearing, since neither requires a response from the test subject. Conventional ABR is an electrophysiological measure of the auditory system's response to sound. A soft click is presented to the ear via earphones or a probe and electrodes record the response as the sound travels from the ear through the auditory nervous system to the brain. Otoacoustic emissions (OAE) measure the integrity of the outer hair cells in the cochlea (inner ear). A soft click is presented and a small microphone placed in the baby's ear canal measures the echo that is returned from the baby's ear. This echo is analyzed to determine how well the inner ear is working. Rule IV(2) requires that one of these two tests be used and that the specific hearing screening equipment used for the screening test must be maintained, calibrated, and used according to the manufacturer's guidelines and testing protocols.

Staff members in the newborn hearing screening program in the hospitals and health care facilities defined in Rule I must be available to accurately screen all babies born in the hospital or health care facility prior to hospital discharge as indicated in Rules IV(1)(a) and (1)(b). This means that accurate screening coverage shall be ensured seven days a week. Rule IV(3) requires that staff members be properly trained in the use of the screening equipment to ensure accuracy of screening results.

RULE V REPORTING NEWBORN HEARING SCREENING RESULTS – PARENTS – PRIMARY CARE PROVIDERS

The newborn hearing screening results obtained by the staff member of the hospital or health care facility must be included in the newborn's medical chart. Both the parents and the baby's primary care provider must be notified of the screening results.

RULE V(1) specifies that the hospital or health care facility must include the newborn hearing screening results in the baby's medical record as well as provide the parent with the written screening results. The department will supply a form for this purpose called the Baby Hearing Test. If the baby's newborn hearing screening results indicate a possible hearing loss, the written notification to the parent must include a recommendation for an audiological assessment.

RULE V(2) requires the hospital or health care facility to provide written notification of the baby's screening results to the baby's primary care provider, including a recommendation for audiological assessment if the newborn hearing screening indicates a possible hearing loss.

RULE VI REPORTING TO THE DEPARTMENT REGARDING NEWBORN HEARING SCREENING AND EDUCATION

Electronic reporting of identifiable, complete screening results is required to implement legislative intent expressed in 53-19-401(2), MCA, to provide the state with the necessary information to effectively plan, establish, and evaluate a comprehensive system of appropriate services for infants and children who are deaf or hard of hearing. The department provides access to a newborn hearing screening and audiological assessment tracking software to facilitate the monthly reporting required by law and specified by Rule VI(2) and (3). All the items required in Rule VI(2) can be recorded in the software in specific data fields or in notes to the screening record. To ensure that Montana is providing universal newborn hearing screening, the screening records will be matched with birth certificates to identify any gaps in screening coverage.

RULE VI(4): If the parent refuses either initial or follow-up newborn hearing screening, it is important to document that this refusal was made after the parent received a standard level of education about the importance of this screening, how the screening is performed, and what happens if the newborn does not pass the initial screening. The department has provided a suggested template for a refusal form for review and adaptation by hospital and health care facility legal counsel. This template entitled "Parental Attestation of Refusal of Newborn Hearing Screening" shall constitute the minimum level of content for any refusal form used by the hospital or health care facility. The hospital or health care facility must provide the department with a faxed copy of the completed refusal form by the fifteenth day of the month following the birth month.

RULE VII HEALTH CARE PROVIDERS – REPORTING TO THE DEPARTMENT REGARDING EDUCATION AND REFERRAL INFORMATION

Because of the short time period in which newborn hearing screening must be completed, monthly documentation of the provision of education and referral is needed from each health care provider defined in Rule I to be able to evaluate timeliness of screening opportunities. A form supplied by the department will facilitate the monthly reporting of the babies' demographic information for matching with Montana birth certificates. A facsimile copy of a completed and signed form indicating that the parent received education about hearing loss, the importance of newborn hearing screening, how it is performed, and where the parent may access the screening from hospitals, health care facilities and other health care providers in the region must be submitted to the department for each newborn attended by the health care provider. The reports shall be submitted to the department by the fifteenth day of each month for the babies born in the previous month.

RULE VIII AUDIOLOGISTS – REPORTING OF AUDIOLOGICAL ASSESSMENTS TO DEPARTMENT – PARENTAL CONSENT FOR REFERRAL TO THE MONTANA SCHOOL FOR THE DEAF AND BLIND

To ensure that Montana's babies are receiving necessary audiological assessments before they are three months of age, it is important that the state's audiologists report audiological assessment results to the department on a monthly basis. The department will provide access to the hearing screening and assessment software used statewide for each audiologist who performs audiologic assessments of babies who did not pass their newborn hearing screenings. This software will allow the audiologist to report all the data required in Rule VIII(1). Audiologists must provide all assessment results to the department for all babies they have assessed in the previous month by the fifteenth day of the next month.

The Montana School for the Deaf and Blind (MSDB) is statutorily responsible for tracking all interventions for deaf and blind children (20-8-102, MCA). The department's newborn hearing screening program is required by law to ensure electronic sharing of audiologic evaluation information of babies diagnosed as deaf or hard-of-hearing to MSDB (53-19-402(2)(f), MCA). The department and MSDB share software designed to track interventions for children with special health care needs. The department will enter the screening and audiologic assessment results of each baby with confirmation of deafness into this software for electronic referral to MSDB.

Rule VIII(2) requires licensed audiologists who conduct an audiological assessment following a newborn hearing screening to request written authorization from the infant's parents to provide the infant's identifying information and test results for subsequent referral for intervention services to the Montana School for the Deaf and Blind. This written authorization is required by the provisions of the Family Educational Rights and Privacy Act (FERPA), 20 USC 1232g et. seq., in instances in which the assessment may be conducted under the Child Find program. Such an authorization will be needed to allow sharing of this information among providers in the future for children who receive services from the Montana School for the Deaf and Blind.

FINANCIAL IMPACT

The modifications, as proposed, are not expected to have financial impact on the department. A significant number of children born in Montana each year are provided health care services through the Medicaid program. However, newborn hearing screening cost is expected to be bundled within standard delivery and newborn treatment charges. In addition, all Montana hospitals providing obstetric services are already screening and reporting the results to the department for the majority of their annual birth cohort, accounting for 93% of all babies born in 2006. At this point in time, there are only two birthing facilities in Montana that have Medicaid reimbursement privileges. They also are expected to bundle the hearing screening costs into their Medicaid charges. In addition, the department's newborn hearing screening program will be assisting those two centers to acquire newborn hearing screening equipment.

5. Interested persons may submit comments orally or in writing at the hearing. Written comments may also be submitted to Gwen Knight, Office of Legal Affairs, Department of Public Health and Human Services, P.O. Box 202951, Helena MT 59620-2951, no later than 5:00 p.m. on January 17, 2008. Comments may also be faxed to (406)444-9744 or e-mailed to dphhslegal@mt.gov. The department maintains lists of persons interested in receiving notice of administrative rule changes. These lists are compiled according to subjects or programs of interest. To be included on such a list, please notify this same person or complete a request form at the hearing.

6. An electronic copy of this proposal notice is available through the Secretary of State's web site at <http://sos.mt.gov/ARM/Register>. The Secretary of State strives to make the electronic copy of this notice conform to the official version of the notice as printed in the Montana Administrative Register, but advises all concerned persons that, in the event of a discrepancy between the official printed text of the notice and the electronic version of the notice, only the official printed text will be considered. The web site may be unavailable at times, due to system maintenance or technical problems.

7. The bill sponsor notice requirements of 2-4-302, MCA, apply and have been fulfilled. The primary bill sponsor was notified by letter dated June 21, 2007, sent postage prepaid via USPS.

8. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct the hearing.

/s/ Kim Kradolfer

/s/ Joan Miles

Rule Reviewer

Director, Public Health and
Human Services

Certified to the Secretary of State December 10, 2007.